



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	Examiner: Erez, Darwin P.
	)	
Flood et al	)	Art Unit: 3761
	)	
Serial No.: 10/091,926	)	
	)	
Filed: 3/5/02	)	
	)	
For: ANTI-G PRESSURE	)	
REGULATOR FOR SUPPLYING	)	
BREATHABLE GAS TO A	)	
PILOT'S FACE MASK AND	)	
<u>METHOD</u>	)	

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DECLARATION OF ROBERT M. HAMILTON

I, Robert M. Hamilton, hereby declare as follows:

1. I am a named co-inventor in the above-identified application. At the request of my counsel, Harold L. Jackson, I have reviewed the Office Action dated April 5, 2004 and in particular (a) the operation of the device disclosed in the primary reference, i.e., the Aldworth et al reference, U.S. Patent No. 5, 199,426 ("Aldworth patent") and (b) the accuracy of the Examiner's statements that during the inhalation the gas pressure supplied to the inlet/outlet port 13 "rises from a predetermined minimum to a predetermined maximum" and during exhalation "the pressure falls from the predetermined maximum to the predetermined minimum to decrease the exhalation effort required by the pilot" referring to valve 33 (inhalation) and valve 65 (exhalation). Column 6, line 64 to Column 7, line 9 (6:64 - 7:9). I am also familiar with an earlier amendment filed in this application.

2. My qualifications for providing the comments herein are as follows:

a. I received a Bachelor of Science degree from Pennsylvania State University in 1954

b. From 1963 to 1975 I was the manager of Life Support Products Engineering for Robertshaw Controls. The plant where I worked was located in Anaheim, California.

c. From 1975 to 1987 I was employed as the Chief Engineer of National Supply Co., a division of Armco. At National Supply we developed and marketed a number of products primarily for use in the oil field industry. Some of the products incorporated diaphragm valves.

d. From 1987 to 1993 I was President of Computer Assisted Engineering located in Orange, California which company developed demand breathing apparatus including the closed circuit breathing apparatus described in my U.S. Patent No. 5,036,841.

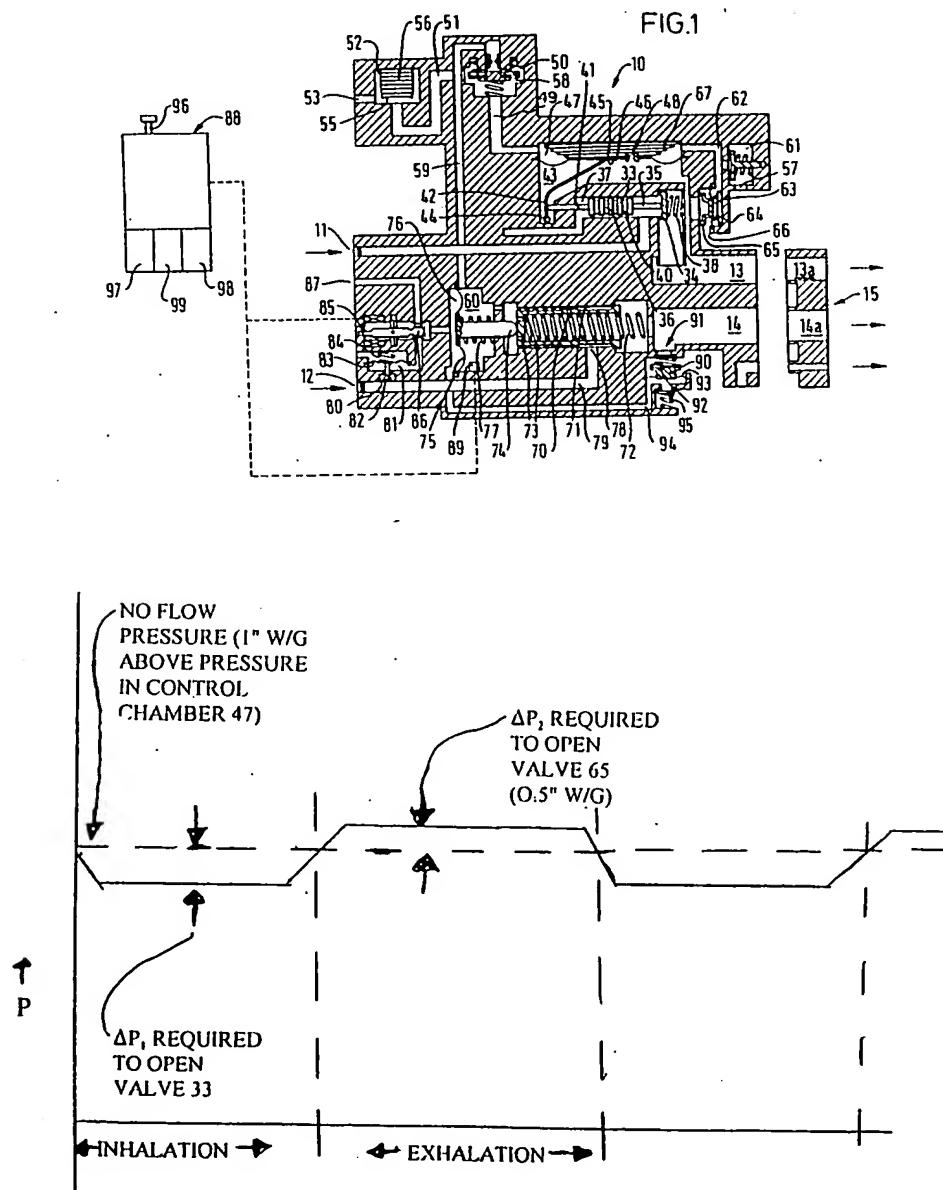
e. From 1993 to 1995 I was President of BSI Services, a company involved in breathing systems apparatus.

f. From 1995 to present I have been and still am the President of Life Support Technology, Inc. Life Support Technology is involved in the design and production engineering of fluid control equipment for the medical profession including the products incorporating inhalation/exhalation valves. I am an inventor or co-inventor of the following U.S. Patents: 6,634,357; 5,806,512; 5,787,882; 5,690,099; 5,036,841 and 3,795,257.

3. Before discussing the Examiner's view of how the 'Aldworth device operates, I would like to point out that the invention described and claimed in the subject application is involved in a Cooperative Research and Development Agreement (CRADA) between co-inventor's, Mike Flood's company, and the U.S. Air Force, in which equipment supplied by the company is being tested by the Air Force for potential use on the next generation of fighter aircraft. As I understand

it, the Air Force's interest is directed to the decreased exhalation pressure at high g-force loads afforded by our invention.

4. To aid the Examiner in understanding the operation of the valves and the pressure control chamber, which control the breathable gas supplied to a pilot's inlet/outlet port 13 of the 'Aldworth device. Fig. 1 of that patent is reproduced below along with a graph of the pressure existing at the inlet/outlet port 13:



5. First, it is noted that the gas pressure in the breathing pressure control chamber 47, whether derived from the aneroid 56, as a function of altitude or from chamber 60 as a function of g-force, once established (along with the several springs, i.e., 46, 36 and 64) sets the device's operational pressures during the inhalation, exhalation and no flow modes. The no flow, i.e., positive safety, pressure noted in the above graph, during which gas is being neither inhaled nor exhaled, is set at one inch water gauge (WG) above the pressure in the control chamber 47 (6:50-59). The incremental pressure increase  $\Delta P_2$  required to open the exhalation valve 69 is specified to be 0.5 inches/WG (6:47-49). The incremental pressure decrease  $\Delta P_1$  required to open the inhalation valve 33 is not specifically stated, but it would probably be of the same order as  $\Delta P_2$ . Second, while the specific incremental values of  $\Delta P_1$  and  $\Delta P_2$  are not important in distinguishing the operation of the subject invention from the Aldworth device, it is important to note that the pressure in the inlet/outlet port 13 of the pilot's face mask does not rise from a predetermined minimum to a predetermined maximum during inhalation nor does the pressure fall from such a predetermined maximum to a predetermined minimum during exhalation.

6. A rise in the inlet/outlet port pressure during inhalation would simply force the diaphragm 46 upwardly allowing the spring 38 to close the valve 33 terminating the inhalation phase. By the same token a decrease in the inlet/outlet port pressure during exhalation would allow the spring 64 to close the valve 65 terminating the exhalation phase. The inlet/outlet port pressure must be greater than the no flow pressure in the above graph in order to open the valve 65. By the same token if a pressure less than the no flow pressure would suffice to open valve 63 then it would remain open during inhalation and exhalation. It is to be noted that depending on the pilot's breathing regime there may be a pause between the time that the pilot ceases to exhale and begins to inhale. During

this pause (not shown in the above graph) the pressure in the inlet/outlet port will return to the no flow pressure.

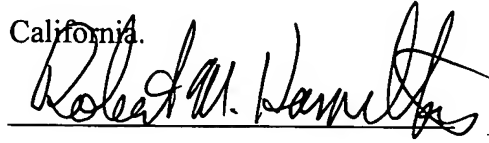
7. Contrast the operation of the Aldworth device, as shown by the above graph, with that of our invention as illustrated in Fig. 7 of the subsection application. The Aldworth device is not designed to provide a decrease in the face mask pressure during exhalation, at any range of g-loads, to reduce the stress on a pilot's system or provide an increase in such pressure during inhalation to insure that the pilot's lungs receive sufficient oxygen, with a reduced exhalation pressure at high g-loads. Instead, to the extent that  $\Delta P_1$  and  $\Delta P_2$  are considered significant, the Aldworth device functions in the opposite manner. To the extent that  $\Delta P_1$  and  $\Delta P_2$  are not considered significant the Aldworth device functions in a manner similar to the state of the art constant pressure systems as pointed out in the amendment dated January 26, 2004.

8. The Air Force has expressed interest in our invention because it functions in a different manner than prior art systems which provide a substantially constant positive pressure, during inhalation and exhalation, thereby placing considerable stress on a pilot's system during exhalation at high g-force.

9. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further, that these statements made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment

or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or document or any patent resulting therefrom.

Signed this 29<sup>th</sup> day of April, 2004 at Irwin, California.

A handwritten signature in black ink, appearing to read "Robert M. Hamilton", written over a horizontal line.

Robert M. Hamilton